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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,660	12/23/1998	RAINER HINTSCHE	60953/119	2492

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/142,660	HINTSCHE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-86,88-91,93 and 94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71-86,88-91,93 and 94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the proposed changes of 08 June 2000 have been approved (see Office action of 01 August 2000), and that correction of drawings cannot be postponed. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

2. The specification contains numerous bibliographic citations, yet it has not been found to contain any statement that the cited documents have been incorporated by reference. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

> Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USQP 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun*

> *Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

> Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

Accordingly, the cited documents are not considered to have been incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 71-86, 88-91, 93, and 94 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,020,110 (Williams et al.) in view of WO 93/22678A2 (Hollis et al.).

7. Williams et al., disclose manufacturing and use of electrodes for the detection of nucleic acids, proteins, antibodies, etc. Column 3, lines 5-6, teaches that the initial gap of the electrode is from, 10 to 75 μm. Column 3, lines 13-18, teach that the electrodes can be treated by bonding, or adsorption of enzymes, as well as specific binding partners "including, but not limited to, antibodies, antigens, DNA or RNA, avidin, biotin, gene probes..." While the gap of the electrode would no doubt diminish by the presence of such binding partners, Williams et al., does not teach that the gap narrows to where it ranges from 1 μm to that of a large molecular complex.

8. Column 3, lines 26-28, teach that the apertures may be of virtually any shape, including circles, squares, rectangles or bands.

9. Column 4, lines 25-30, teaches separating working and reference electrodes via a polyester substrate, which is construed as serving as an insulating material.

10. Column 3, lines 44-51, teaches of the working electrode and counter electrode being comprised of silver and gold. Column 4, lines 27-29, teaches the working and counter electrode can comprise carbon and that a reference electrode can comprise silver.

11. The aspect that the electrodes are printed on a flat polyester substrate (column 4) meets the imitation that the electrodes constitute "a layer on a planar insulating support material."

12. Hollis et al., page 11, teach that while the gap in the insulating material is 2 μm wide, "[m]ost importantly, the spacing between the upper and lower electrodes is of the order of the length (or diameter in solution) of the target DNA molecule. Therefore, the ratio of the target DNA to solvent in the interelectrode space is high, thereby giving greater sensitivity to the presence or absence of the target DNA during an electrical measurement."

13. Hollis et al., page 25, teaches:

> Materials which can be incorporated into the surface of the electrodes to provide for direct attachment of probes include electrometal materials, such as gold, niobium oxide, iridium oxide, platinum, titanium, tantalum, tungsten and other metals. These electrometals are capable of forming stable conjugates directly on the plate surface by linkages with organic thiol groups incorporated into the probe, as described in Whitesides et al. (1990) Langmiur 6:87-96 and Hickman et al. (1991) J. Am. Chen. Soc. 113:1128-1132, both of which are incorporated by reference herein.

14. Hollis et al., Figure 1, depicts a device where the electrodes are arranged in a substantially planar manner as well as being stacked. The aspect of the electrode leads being surrounded by a non-conductive substrate speaks to their being insulated from one another.

15. In view of the detailed teachings of the prior art of record, and the motivation for arrange the electrodes such that the gap between the electrodes approximates the size of a large

molecular complex, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the sensor and methodologies of Hollis et al., into the disclosure of Williams et al., as such would have resulted in greater sensitivity. Accordingly, and in the absence of convincing evidence to the contrary, claims 71-86, 88-91, 93, and 94 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,020,110 (Williams et al.) in view of WO 93/22678A2 (Hollis et al.).

Response to argument

16. Agreement is reached in that Williams does not each all of the limitations of the claimed invention, however, the instant rejection has not been made under 35 USC 102, which is directed to issues of anticipation, but rather, under 35 USC 103(a), which is directed to matters of obviousness.

17. Argument is advanced that Williams teaches having apertures formed along a continuous electrode and as such the array of apertures does not constitute "at least two electrode structures."

18. The above argument has been fully considered and ahs not been found persuasive towards the withdrawal of the rejection. The aspect of having multiple apertures arrayed along electrodes, even if the electrode material is continuous, is considered to meet the limitation that there are at least two electrode structures. In support of this interpretation, attention is directed to page 4 of the specification, which is reproduced below in pertinent part.

> The ultra-microelectrode arrays may consist of thin layers of noble metals such as gold, platinum or iridium, or alternatively carbon materials, or may contain these materials. They are particularly advantageously applied to planar insulating support materials such as silicon compounds, glass, ceramic or organic polymers, but may also, for planarization and mechanical support, be buried or incorporated in these materials. Two mutually insulated ultra-microelectrodes can be brought together optimally, as represented in fig.

1, for example using bands or parallel strips or meandering and round or coiled structures as well as using finger-like interdigital arrangements at distances of preferably less than 1 µm.

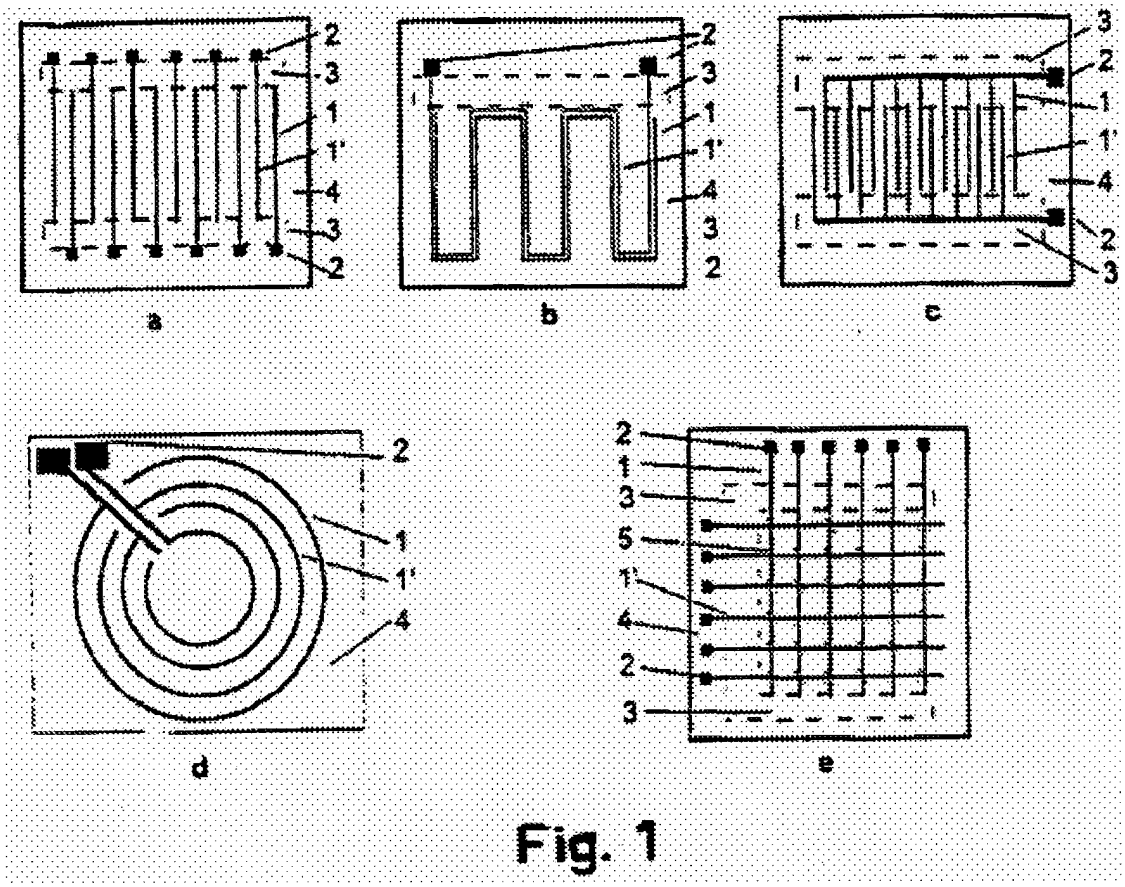

Fig. 1

As can be seen in Fig. 1b, 1c, and 1d, there are but two electrodes present. As is plainly evident above, the ultra-microarray encompassed the very embodiment disclosed by the prior art.

19. Argument is advanced that the electrodes of Williams are situated at the bottom of wells and as such, there is no gap between the electrodes.

20. The above argument has been fully considered and has not been found persuasive. As presented above, Williams teaches printing the different electrodes upon a planar surface. By default there must be a gap between them otherwise there would be but one electrode. Assuming *arguendo* that the gap between the electrodes is not that recited in the present claims, Hollis et

al., Fig. 4 clearly teach electrode structures that are insulated from one another and where the gap between electrodes is about 2 μm.

21. At page 12 of the response argument is advanced that the array of electrode structures of Hollis et al., are not in a substantially planar manner. Applicant's representative goes on to recite specific distances.

22. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. As an initial matter, claim 71 does not recite the limitation "substantially planar." Further, a review of the disclosure fails to locate such a phrase. Assuming *arguendo* that basis of the phrase were to exist, applicant is arguing limitations (e.g., thicknesses) that are not recited in the claims.

23. For the above reasons, and in the absence of convincing evidence to the contrary, claims 71-86, 88-91, 93, and 94 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,020,110 (Williams et al.) in view of WO 93/22678A2 (Hollis et al.).

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

25. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
17 March 2005